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Anh Nguyen
01/22/04 01:54 PM

To: NCIC HPV@EPA
cc:
Subject: Environmental Defense comments on 4-(1-methyl-1-phenylethyl)-N-[4-(1-methyl-1-phenylethyl)phenyl]aniline (CAS# 10081-67-1)

----- Forwarded by Anh Nguyen/DC/USEPA/US on 01/22/2004 01:50 PM -----

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01/22/2004 11:34 AM

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Subject: Environmental Defense comments on 4-(1-methyl-1-phenylethyl)-N-[4-(1-methyl-1-phenylethyl)phenyl]aniline (CAS# 10081-67-1)

(Submitted via Internet 1/22/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and mark_thomson@cromptoncorp.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 4-(1-methyl-1-phenylethyl) -N-[4-(1-methyl-1-phenylethyl)phenyl]aniline (CAS# 10081-67-1). In the test plan, this chemical is referred to as 4,4'-Bis(alpha, alpha-dimethylbenzyl) diphenylamine.

The Crompton Corporation, in response to EPA's High Production Challenge, has submitted Robust Summaries and a Test Plan describing available data for and proposed testing of 4-(1-methyl-1-phenylethyl) -N-[4-(1-methyl-1-phenylethyl)phenyl]aniline (CAS# 10081-67-1) needed to fulfill SIDS elements for this compound.

Our review indicates this submission represents a minimal effort to comply with the objectives of the HPV Challenge. We offer the following General and Specific Comments to support our assessment of this submission.

General Comments:

The Test Plan provides little or no information describing the uses of 4-(1-methyl-1-phenylethyl)-N-[4-(1-methyl-1-phenylethyl)phenyl]aniline or its potential for human and/or environmental exposure. There is no mention of production volume, potential for and efforts to contain its release into the environment, transport or uses in consumer products. The minimal background information presented indicates this compound is used as an antioxidant and thermal stabilizer in plastics, adhesives and lubricants, although no mention is made of the concentration at which this chemical may be used in such products or the specific types of products in which it may be used. Further, no information is provided to indicate the level of release from products in which it is used. While such data are not required under the program, they provide important background information necessary to an understanding of potential risks posed by this chemical.

With the exception of the data submitted in support of the Ames Test, the Robust Summaries submitted to address specific SIDS elements requested under the HPV Challenge also provide minimal information. Further, most

studies are not referenced, and the few referenced studies are somewhat dated and were not conducted under GLP. Given the dearth of reliable studies of this compound, we support the studies proposed to address repeat dose toxicity, chromosomal aberrations, and reproductive and developmental toxicity.

Specific Comments:

1. A list of synonyms and/or chemical names is not provided for 4-(1-methyl-1-phenylethyl)-N-[4-(1-methyl-1-phenylethyl)phenyl]aniline. This is of particular interest because the chemical name used in this submission -- 4,4'-Bis(alpha, alpha-dimethylbenzyl) diphenylamine -- differs from that used in the EPA web-site listing of the HPV chemicals for which submissions have been received.

2. The trade name for 4-(1-methyl-1-phenylethyl) -N-[4-(1-methyl-1-phenylethyl)phenyl]aniline is given as "Naugard 455" in several Robust Summaries, but not in the Test Plan and no uses are described for Naugard 455.

3. In citing data for melting point and boiling point, the reader is referred to the Safety Data Sheet. The Safety Data Sheet is obviously not a primary reference. The primary references for these data should be cited.

4. Biodegradation is modeled and the results of that study are given in the Test Plan and Robust Summaries as "not readily biodegradable". The actual quantitative results of the modeling should be provided. If the model can not provide such a quantitative estimate, that fact and an explanation should be clearly stated in the Test Plan.

5. References provided in the Test Plan are limited to guidelines and computer modeling methods. References provided in the Robust Summaries are similarly limited, or in a few cases refer to "internal company documents". Given the very brief descriptions of the specific studies in the Robust Summaries, the reader is provided very limited data and no way to obtain additional information. These deficiencies need to be addressed.

Thank you for this opportunity to comment.

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